UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE INTERCEPT PHARMACEUTICALS, INC. SECURITIES LITIGATION	:	14 Civ. 1123 (NRB) ECF Case **ORAL ARGUMENT REQUESTED**

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT

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INTRODUCTION

In its opening brief, Defendant Intercept Pharmaceuticals, Inc. ("Intercept") offered a compelling explanation for its initial decision not to disclose that NIDDK had identified lipid abnormalities in the FLINT trial of OCA: At that time, Intercept had no data from which it could make an informed assessment of the magnitude or potential importance of the issue. Especially given that the market already understood that lipid abnormalities were associated with OCA, and that NIDDK approved its press release, Intercept made a reasonable decision to wait for more particular information before discussing the issue publicly. The facts do not support the required strong inference that the risk of misleading investors was so obvious that Intercept must have been aware of it. Plaintiffs have failed to plead scienter.

In an effort to stave off dismissal, Plaintiffs mischaracterize the law and seek to reframe Intercept's arguments. First, and most prominently, Plaintiffs misstate the applicable standard for scienter, contending that knowledge of an undisclosed material fact automatically establishes scienter. But that formulation applies only where defendants knew information directly contrary to their statements (and thus intent to deceive is fairly presumed). In cases such as this one—where the claim is that an accurate disclosure was incomplete—knowledge of the omitted fact is not enough, and a plaintiff must plead facts supporting a strong inference that the danger of misleading investors was so obvious that the defendant must have known it. *See infra* at 3-5. Plaintiffs fail to do so.

In an effort to bolster their flawed scienter analysis, Plaintiffs spend much of their brief arguing that the omission here was material. But this is a straw man: Intercept has not claimed (for purposes of this motion) that the omission was not material. Plaintiffs also try to shoehorn this case into the rubric of the Supreme Court's decision in *Matrixx*, which held that lack of

statistical significance does not automatically negate materiality or scienter. This too is a straw man: Intercept's argument does not turn on the lack of statistical significance, but rather on the complete absence of *any* data to assess the importance of the lipid issue.

Finally, Plaintiffs mischaracterize the facts in an effort to avoid the obvious compelling inference that Intercept lacked intent to defraud. Among other things, they insist that NIDDK did not approve Intercept's press release, but the record shows that after Intercept explained its decision not to mention lipids and provided a draft, Dr. Sherker wrote "looks good" and offered only minor edits. And they claim that Intercept did not disclose lipid abnormalities in a prior trial of OCA, when it plainly did.

Plaintiffs' attempts to reframe Intercept's arguments and to rewrite the record fail. For these and other reasons set out below and in the opening brief, the Complaint should be dismissed for failure to plead fraudulent intent.

ARGUMENT

I. PLAINTIFFS MISSTATE THE APPLICABLE STANDARD FOR SCIENTER

Plaintiffs argue that Intercept's mere knowledge of NIDDK's lipid finding automatically establishes scienter, and that Intercept's reasons for initially deciding to wait for actual data or more specific information before discussing the lipid issue are irrelevant. *See* Pl.'s Opp. at 2, 16 (citing *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000) ("[D]efendants' knowledge of facts or access to information contradicting their public statements" will support scienter)). To be sure, knowledge alone suffices where—as in all of the inapposite cases Plaintiffs cite—a known fact was *directly contrary* to what the defendant said, making it fair to infer intent to deceive. *See, e.g.*, *In re Delcath Sys., Inc. Sec. Litig.*, No. 13 Civ. 3116, 2014 WL 2933151, at *12 (S.D.N.Y. June 27, 2014) (defendants touted safety and chances for FDA approval of medical device but

knew of deaths in clinical trials and severe FDA criticism); *In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 639 (S.D.N.Y. 2008) (defendants touted safety of drug but knew of "multiple studies that linked" drug to adverse cardiovascular events); *In re Ambac Fin. Grp., Inc. Sec. Litig.*, 693 F. Supp. 2d 241, 267-268 (S.D.N.Y. 2010) (Buchwald, J.) (defendants stated that company had "maintained the same conservative standards over the years" without disclosing that it had lowered its underwriting standards; and stated that company was "very solid and very safe" even though they "knew about significant deterioration of the company's CDO portfolio").[1] This "specific contradictory information" rubric, *Ambac*, 693 F. Supp. 2d at 267, is inapplicable here.

Plaintiffs do not allege that Intercept knew facts directly contrary to its statements. Rather, Plaintiffs allege that Intercept's statements were accurate but incomplete, and that Intercept knew a material fact that it omitted (*i.e.*, that NIDDK had found lipid abnormalities).[2] In such cases, mere knowledge of the omitted fact is not enough to infer scienter; a plaintiff must plead additional facts supporting a strong inference that the danger of misleading investors was so obvious that the defendant must have known it. In *Kalnit v. Eichler*, the Second Circuit clearly distinguished between the scienter standard applicable in misrepresentation cases and omission cases. 264 F.3d 131, 144 (2d Cir. 2001) (rejecting plaintiffs' reliance on misrepresentation cases and observing that "[t]here can be no question that a corporation's public statements must be truthful. Here, however, plaintiff's claim lies in non-disclosure."). The court went on to hold that even though the defendant had failed to disclose known material

[1] *See also, e.g., In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 571 (S.D.N.Y. 2011) (defendant had been ordered to obtain a formal risk assessment for its candidate drug, the results of which put the drug's commercial viability in "extreme peril," but made statements strongly implying that these events did not occur).

[2] Intercept's statement—that NIDDK had stopped the trial because it found OCA had demonstrated efficacy—was indisputably true.

information about a merger agreement—namely that it had released a principal shareholder from a standstill agreement preventing him from proposing mergers so that he could pursue superior proposals[3]—the omission was not reckless. Because the public already knew that the defendant could accept superior proposals, the duty to disclose was "not so clear," and therefore the omission alone did not supply the required *strong* inference of scienter. *Id.* at 143-144. *In re Canandaigua Sec. Litig.*, 944 F. Supp. 1202 (S.D.N.Y. 1996) is to the same effect:

> *It is not enough for plaintiffs to allege that defendants knew that the disclosures did not reveal the pricing strategy or that the omitted information was material, for that alone does not suggest "conscious misbehavior or recklessness."* Absent some allegation that defendants knew or were highly unreasonable in not knowing that they were doing something illicit, the complaint fails to adequately plead scienter.

Id. at 1213-14 (emphasis added and internal citations omitted); *see also, e.g.*, *In re Open Joint Stock Co. "Vimpel-Commc'ns"*, No. 04 Civ. 9742, 2006 WL 647981 (S.D.N.Y. Mar. 14, 2006) (Buchwald, J.) (no scienter where defendant knew of undisclosed foreign tax audit, even if audit had been material). *Cf. In re Carter-Wallace, Inc. Sec. Litig. (Carter-Wallace II),* 220 F.3d 36, 40-42 (2d Cir. 2000) (scienter was not pleaded because "it was not reckless for Carter–Wallace to believe [its] assertions to be true").[4] Thus, the mere fact that Intercept knew about the NIDDK

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[3] The initial lower court decision in *Kalnit* concluded after extensive analysis that the omitted information was material and that the defendant had a duty to disclose it. 85 F. Supp. 2d 232, 238-240, 245 (S.D.N.Y. 1999).

[4] Decisions from several other courts of appeals are consistent with *Kalnit* and hold that mere knowledge of an omitted material fact does not provide a strong inference of scienter. *See Minn. Firefighter's Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1030 (8th Cir. 2011) (known, undisclosed production problems were material, but "the inference of scienter is [not] as compelling as the more innocent, simpler inference that the defendants did not believe they had a continuing duty to disclose information [because they believed the problems were immaterial]"); *City of Philadelphia v. Fleming Cos.*, 264 F.3d 1245, 1261 (10th Cir. 2001) ("[T]o establish scienter in a securities fraud case alleging nondisclosure of potentially material facts, the plaintiff must demonstrate: (1) the defendant knew of the potentially material fact, and (2) the defendant knew that failure to reveal the potentially material fact would likely mislead investors."); *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F. 3d 751, 758 (1st Cir. 2011) (even though defendants were aware of regulatory changes and admitted in hindsight that they should have disclosed them, court dismissed for lack of scienter because the "inferences are stronger that defendants did not knowingly or recklessly risk misleading the reasonable investor").

lipid observation does not establish a strong inference of scienter, even if it was material.[5]

Plaintiffs must, at a minimum, plead additional facts supporting recklessness, *i.e.*, conduct "which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger [of misleading investors] was either known … or so obvious that the defendant must have been aware of it." *Kalnit*, 264 F.3d at 142 (quoting *Carter-Wallace II*, 220 F.3d at 39); *accord In re Duane Reade Inc. Sec. Litig.*, No. 02 Civ. 6478, 2003 WL 22801416, at *9 (S.D.N.Y. Nov. 25, 2003) (Buchwald, J.), *aff'd sub nom. Nadoff v. Duane Reade, Inc.*, 107 F. App'x 250 (2d Cir. 2004) (summary order). As explained in Intercept's opening brief and in Section III below, Plaintiffs cannot support that inference; or, alternatively, any such inference is not as cogent and compelling as the inference that Intercept did not ignore an obvious danger of misleading investors and instead acted reasonably.[6]

II. PLAINTIFFS CONFLATE MATERIALITY WITH SCIENTER

Plaintiffs compound their invocation of a flawed scienter rubric by devoting much of their brief to arguing that the preliminary lipid information that NIDDK provided to Intercept was material. But as shown above, in a case such as this one, materiality is not the linchpin of the scienter analysis; rather, it is whether the danger of misleading investors by the omission was

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[5] *In re Delcath* (*see* Pl.'s Opp. at 17) is not to the contrary. Plaintiffs claim the court rejected the scienter framework that Intercept proposes. But a careful reading of the case shows this is not so. For one thing, the case involved allegations that the defendants knew their statements were inaccurate, not simply that they were incomplete. 2014 WL 2933151, at *12. For another, while the passage that Plaintiffs cite says that the "obvious danger of misleading investors" is not the standard for scienter in the Second Circuit, the decision on which the court relied—*ECA*—clearly embraces that test as one way to show scienter. *ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 198, 202-203 (2d Cir. 2009). Finally, the *Delcath* court—immediately after the passage Plaintiffs cite for the proposition that Intercept's reasons for its conduct are irrelevant—went on to consider the claim that there was no strong inference of scienter because "management honestly believed its positive view of the data from its trials," and rejected it only because the record did not support it. 2014 WL 2933151, at *12.

[6] Plaintiffs rely on a sound bite to distance themselves from *Vertex*, but that case is on point. The court held that certain omitted information (concerning the drug's toxicity) was material, *In re Vertex Pharm., Inc., Sec. Litig.*, 357 F. Supp. 2d 343, 351 (D. Mass. 2005), but nevertheless held that knowledge of that toxicity was not enough to establish scienter because defendants reasonably could have believed the drug would gain approval. *Id.* at 352, 355.

so obvious that the defendant must have known it. Indeed, for purposes of this motion only, Intercept does not even contest materiality. The argument is beside the point.

Relatedly, Plaintiffs contend that *Matrixx* undermines Intercept's arguments and the cases on which it relies, including *Carter-Wallace II*. However, *Matrixx* held only that there is no categorical rule that lack of statistical significance automatically negates materiality or scienter. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011). But Intercept nowhere argued that it lacked scienter because it did not have *statistically significant* lipid data. Rather, Intercept had no data or information *at all* beyond the mere fact that NIDDK had identified abnormalities (which already were known to be associated with OCA). Meanwhile, contrary to Plaintiffs' suggestion that *Matrixx* invalidates much of the authority that Intercept cites, courts in this Circuit continue to cite and apply *Carter-Wallace II* and other pre-*Matrixx* cases with respect to the standard for pleading scienter.[7] And in any case, Intercept's arguments proceed from basic definitions of recklessness that both pre- and post-date *Matrixx*, and do not depend on any case's discussion of statistical significance.

III. THE ONLY (AND THE MOST) COGENT AND COMPELLING INFERENCE FROM THE FACTS HERE IS THAT INTERCEPT LACKED SCIENTER

Plaintiffs fare no better when they finally join issue with the argument Intercept *does* make, namely that Plaintiffs have not pleaded facts supporting a strong inference that omission of NIDDK's lipid finding posed an obvious danger of misleading investors, let alone shown that any such inference is "at least as compelling as [the] opposing inference" that Intercept acted reasonably. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

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[7] *See, e.g.*, *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 39 (2d Cir. 2012) (summary order) (citing *Carter-Wallace II*); *Koncelik v. Savient Pharm., Inc.*, 448 F. App'x 154, 155 (2d Cir. 2012) (summary order) (affirming, post-*Matrixx*, a pre-*Matrixx* decision); *Davison v. Ventrus Biosciences, Inc.*, No. 13 Civ. 3119, 2014 WL 1805242, at *11 (S.D.N.Y. May 5, 2014) (citing *Carter-Wallace II*); *S.E.C. v. Boock*, No. 09 Civ. 8261, 2011 WL 3792819, at *21 (S.D.N.Y. Aug. 25, 2011) (citing *Carter-Wallace II*).

First, Plaintiffs' insistence that NIDDK "never approved Defendants' press release or public statements" is inconsistent with the record. Intercept shared its draft press release with Dr. Sherker, explained that "[w]e don't think that without the specific data, we can comment on the lipid changes," CAC ¶ 35, and sought his input. Dr. Sherker suggested only minor edits, raised no concerns about the omitted information, and said, "This looks good." Friedman Decl., Ex. B, May 22, 2014 Form 8-K, at 42. The observation that NIDDK had no authority to provide *legal advice* on disclosure duties, Pl.'s Opp. at 19-20, is another red herring. The apparent sign-off of the government agency that conducted FLINT, which alone had access to the lipid data at that point, supports the inference that Intercept lacked intent to defraud.[8]

Second, Plaintiffs downplay the importance of the lack of data or specific information about the lipid issue by arguing that NIDDK had identified a "safety risk" that necessarily was material. Leaving aside that Plaintiffs once again conflate materiality with scienter, NIDDK is not alleged to have stated, at any point, that there was a safety risk.[9] To the contrary, Dr. Sherker was clear that the lipid finding was a secondary reason for NIDDK's decision. *See* CAC ¶¶ 34, 36 ("the NIDDK decision to terminate therapy was primarily due to the efficacy effect"). Plaintiffs have failed to plead that there was a clear "safety risk" that, if not disclosed, posed an obvious danger of misleading investors. Particularly where the association between OCA and lipid abnormalities already was known, it was reasonable for Intercept to wait until it had actual data or at least more concrete information before commenting. *See In re Elan Corp. Sec. Litig.*,

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[8] Dr. Shapiro's statement in response to NIDDK's proposed press release that the lipid information "is specific and [] will cause issues," CAC ¶ 49, does not reflect any concern for effect on stock price but rather reflects the concern Dr. Shapiro previously expressed, that Intercept would be put in the untenable position of having to comment on NIDDK's finding when it had no "specific" data or information to guide its comments. CAC ¶ 35.

[9] Tellingly, Plaintiffs provide no direct support for their safety-related assertions. *E.g.*, Pl.'s Opp. at 4 (asserting with no citation that Dr. Shapiro called Dr. Sherker to discuss "NIDDK's findings regarding the efficacy *and safety* of OCA" (emphasis added)).

543 F. Supp. 2d 187, 217 (S.D.N.Y. 2008) (no scienter because "[d]efendants are permitted a reasonable amount of time to evaluate potentially negative information and to consider appropriate responses").

Plaintiffs' suggestion that Intercept's announcement of the efficacy results somehow undermines its position on not disclosing the lipid abnormalities is an attempt to compare apples with oranges. Unlike the lipid finding, the FLINT interim efficacy results were measured by a rigorous, pre-established protocol known to Intercept. Friedman Decl., Ex. B, May 22, 2014 Form 8-K, at 52, 60 (interim results showed improvement in the primary endpoint to a "p value" of 0.0024 on an intention-to-treat basis, with primary endpoint specifically "defined as a decrease in the NAFLD Activity Score of at least two points with no worsening in fibrosis"); *see also* Def.'s Mem. 5-9 & nn.3-5. It was not reckless to share one but not the other.[10]

Third, the market already knew about the association between OCA and lipid abnormalities, so there was no obvious danger of misleading investors in not disclosing the mere fact that such abnormalities had been observed in FLINT. Plaintiffs argue that this is a "truth on the market" defense and is therefore inappropriate for resolution on a motion to dismiss.[11] But courts clearly consider the prior availability of information in evaluating scienter on a motion to dismiss. *See Kalnit*, 264 F.3d at 139 (nondisclosure of waiver of agreement preventing stockholder from developing competing merger proposal was not reckless, where market already understood that company could accept superior bids); *In re GeoPharma, Inc. Sec. Litig.*, 399 F.

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[10] *In re Amylin*, which Plaintiffs cite, dealt with the sufficiency of safe harbor statements and is factually inapposite. *In re Amylin Pharm., Inc. Sec. Litig.*, 01CV1455, 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003).

[11] The "truth on the market" doctrine—like much of Plaintiffs' brief—goes to materiality, and not scienter. *See Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 167 (2d Cir. 2000) ("[Under] the so-called 'truth on the market' corollary to 'fraud on the market' …, a misrepresentation is immaterial if the information is already known to the market because the misrepresentation cannot then defraud the market.").

Supp. 2d 432, 451-452 (S.D.N.Y. 2005) (where already-public omission was "incapable of defrauding investors, that, in itself, negates the inference of intent to defraud.").[12]

Moreover, Plaintiffs misstate the record in contending that Intercept did not disclose lipid abnormalities in the earlier trial, but only disclosed the absence of any "clear, concerning safety signals." Pl.'s Opp. at 22. To the contrary, *on the very same page* (*see* Friedman Decl. Ex. D, Form S-1, at 32) Intercept specifically disclosed that trial subjects taking OCA showed "a decrease in triglycerides at the 50mg dose, and an increase in LDL; and decrease in HDL at 50mg." *Id.*; *compare with* CAC ¶ 34 (alleging Dr. Sherker informed Dr. Shapiro generally of "increased total cholesterol, increased LDL cholesterol and decreased HDL"). Plaintiffs fail to appreciate that the mere existence of lipid abnormalities such as these does not automatically equate to a "safety" issue, a misunderstanding that pervades their brief. [13]

Fourth, Plaintiffs have no answer to Intercept's point that its promise to release the full results of FLINT as soon as they became available underscores its lack of fraudulent intent. They recite a general statement of the disclosure standard, but that has nothing to do with the

[12] Plaintiffs fail to distinguish *GeoPharma*. According to Plaintiffs, the case would be on point only if Intercept—impossibly—already had disclosed NIDDK's finding. But they cite no case holding that scienter is negated only where the *exact* information in the *exact* form as that alleged to have been withheld was previously disclosed. Indeed, that was not even the case in *GeoPharma* itself. The defendant there was not accused of concealing the fact of FDA approval for its product as Plaintiffs say, Pl.'s Opp. at 22, but rather of misleadingly suggesting the approval had been for a drug rather than a medical device. *In re GeoPharma*, 399 F. Supp. 2d at 449-450. Here, Intercept had previously disclosed the association between OCA and lipid abnormalities, which was the only information the market possibly could have gleaned from the mere fact of NIDDK's observation.

[13] Plaintiff mischaracterize the prior trial as one "regarding diabetes." Pl.'s Opp. at 21-22. In fact, it was a trial in patients with non-alcoholic fatty liver disease (NAFLD)—a precursor to NASH—who *also* had type 2 diabetes. Friedman Decl., Ex. D, Form S-1, at 31; *see also* Def.'s Mem. at 6-7 n.4. This NAFLD study was the basis for using OCA in FLINT in the first place. Friedman Decl., Ex. E, Jan. 13, 2014 Form 8-K, at 5. In any event, Plaintiffs' quibbles about the differences between the NAFLD trial and FLINT are beside the point. Intercept does not argue the studies were identical, only that Intercept reasonably believed that (as Dr. Shapiro told Dr. Sherker) the association between OCA and lipid abnormalities was already known to the market. *See, e.g.*, CAC ¶ 34.

separate scienter inquiry, or the factual circumstances here.[14]

IV. PLAINTIFFS HAVE NOT PLEADED MOTIVE AND OPPORTUNITY

Plaintiffs' attempt to plead motive and opportunity also fails. The only basis cited for such a theory is that Intercept had a secondary offering scheduled *months* after the events in question. This generalized business motive is patently insufficient. *See Kalnit*, 264 F.3d at 139; *GeoPharma*, 399 F. Supp. 2d at 449-450. *In re Time Warner* is not the contrary. That case involved a material omission *about the offering itself*, namely the fact that the SEC had rejected an earlier proposal to do a different type of offering. *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 262, 269-271 (2d Cir. 1993).[15] In any event, there is no plausible inference that—absent a single supporting factual allegation—Intercept's initial decision not to mention lipids was somehow motivated by or even connected to a planned secondary offering that was months down the road. *See In re Open Joint Stock Co.*, 2006 WL 647981, at *8 (motive and opportunity theory "plainly deficient" where defendant allegedly omitted foreign tax inspection so that it "could sell $300 million in debt notes" several months later "on the best possible terms").[16]

CONCLUSION

The Consolidated Amended Complaint should be dismissed in its entirety with prejudice.

Dated: October 13, 2014 Respectfully submitted,

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[14] Plaintiffs also argue that Dr. Pruzanski's statement that "he did not 'want to overplay where we are" during the January 9, 2014 conference call, Defs' Mem. at 21, should be disregarded because it was made in the context of discussing the number of patients diagnosed with NASH, not the efficacy finding. But Dr. Pruzanski's statement is nevertheless indicative of his general mindset of tempering his optimism with caution.

[15] This Court's decision in *Complete Management* is even further afield. The motive and opportunity allegations there involved millions of dollars of insider trading, as well as a scheme to use "unlawful recognition of phony receivables" to boost the company's stock price as part of a scheme to generate additional receivables. *In re Complete Mgmt. Inc. Sec. Litig.*, 153 F. Supp. 2d 314, 327-329 (S.D.N.Y. 2001).

[16] Because Plaintiffs do not plead primary liability, the control person claims fail. *See* Def.'s Mem. at 22.

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